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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,707

08/25/2006

Michitaka Sato

2006_1414A

3825

513 7590 06/25/2008

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EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,707	Applicant(s) SATO ET AL.	
	Examiner Erich A. Leeser	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,8-11,13-16 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 3-5,12 and 17-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6 and 8-25 are currently pending and under examination. This is the second action on the merits and it is in response to Applicant's Remarks and Amended Claims dated March 3, 2008 in which Applicant cancelled claim 7.

Claim Rejections 35 U.S.C. § 112

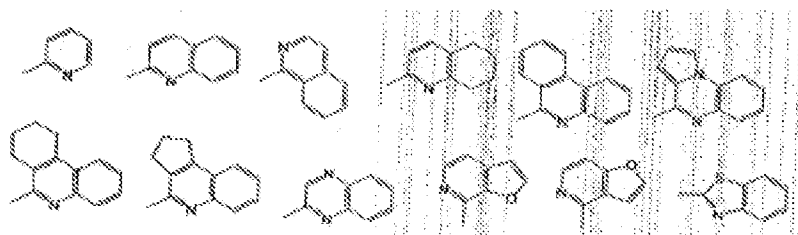
Examiner previously rejected claims 1 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Specifically, Examiner rejected claim 1 because the claim language is unclear as to the number or range of atoms included in the “remainder of the group” of variable group B. Applicant's have provided extensive argument as to what the inventors knew and didn't know at the time the application was filed and a declaration from one of the inventors. The only thing that Applicant submitted that in any way answers Examiner's rejection is the twelve moieties provided by Applicant on page 15 of the Remarks. Examiner currently maintains this rejection, but would drop the rejection if Applicant replaced the indefinite and ambiguous present definition of Ar:



with the structure of these twelve moieties:

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in claim 1 if there is

support in the application as filed.

(b) Examiner rejected claim 17 because “therapeutic method of irritable [bowel] syndrome” was unclear for a multiplicity of reasons. Based on Applicant’s claim amendment, however, Examiner withdraws this rejection.

Examiner previously rejected claims 16-22 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not enable the instant compounds to treat irritable bowel syndrome, depression and the other diseases and conditions listed in claim 16 comprising administering a therapeutically-effective amount of a compound of formula (I) or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Examiner now withdraws this rejection based on Applicant limiting these claims to the treatment of irritable bowel syndrome only, Applicant's *in vitro* and *in vivo* assays in the specification, and the journal articles showing the correlation between this class of compounds and the treatment of irritable bowel syndrome.

Claim Rejections 35 U.S.C. § 103

Examiner previously rejected claims 1-2, 7, 9-11, 13 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Matsuoka, et al., Canada Patent No. 2431406.

Applicant argues that the amendment of claim 1 removing hydrogen from the definition of X¹ removes the reference from being an obvious variant of the instant claims. Examiner disagrees and maintains the rejection because X¹ can still be lower alkyl and hydrogen and methyl are homologs of one another. It is well-established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 USPQ 137 (CCPA 1978) and *In re Lohr*, 137 USPQ 548, 549 (CCPA 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity.

Examiner previously rejected claims 1, 6, 8-11, 13-15 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Modica et al., *High Potent and Selective Arylpiperazine Derivatives as Ligands for the 5-HT_{1A} Receptor*, Bioorganic & Medicinal Chemistry Letters, 10(10), 1089-1092 (2000).

Applicant argues that the compounds in the reference cited by Examiner “have a pyrimidine ring at their terminal” and Applicant’s testing has indicated that such compounds are “weak in 5-HT₃ antagonistic activity, and can be said to be unsuitable for the treatment of IBS which is to be effectively treated by the cooperation of 5-HT_{1A} agonistic activity and 5-HT₃ antagonistic activity.

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Examiner finds this use argument unpersuasive if the compounds of the reference are obvious variants of the compounds of the instant claims. Examiner notes that pyrimidine is not one of the twelve moieties provided by Applicant on page 15 of the Remarks. If Applicant amends the claims as suggested by Examiner, *supra*, then the reference would not read on the rejected claims.

Examiner previously rejected claims 1, 6-7, 9-11, 13-16 and 23-25 under 35 U.S.C. § 103(a) as being unpatentable over Guccione, et al., *3D-QSAR Using "Multiconformer" Alignment: The Use of HASL in the Analysis of 5-HT1A Thienopyrimidinone Ligands*, Journal of Computer-Aided Molecular Design, 14(7), 647-657 (2000).

Applicant essentially makes the same arguments with regards to this reference as with Modica et al., *High Potent and Selective Arylpiperazine Derivatives as Ligands for the 5-HT1A Receptor*, Bioorganic & Medicinal Chemistry Letters, 10(10), 1089-1092 (2000).

As such, Examiner's response is the same with regards to this reference and maintains the rejection.

Claim Objections

Claims 3-5, 12, and 17-22 are objected to as being dependent upon a rejected independent claim, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

**/James O. Wilson/
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